UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

ABDELMAJID ELMAZOUNI, et al.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	Case No. 3:16-cv-00574-M
	§	
MYLAN, INC., et al.,	§	
	§	
Defendants.	§	
	§	

MEMORANDUM OPINION AND ORDER

Before the Court is a Rule 12(b)(6) Motion to Dismiss [ECF # 5], filed by Defendants Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc. For the reasons stated, the Motion is GRANTED.

Background

This is a product liability action arising out of the death of Lisa Elmazouni ("Decedent"), allegedly as a result of the toxic effects of fentanyl, a Schedule II controlled substance used for the treatment of persistent, chronic pain. Pl. Compl. [ECF # 1] at 5, ¶¶4.03-4.04. Plaintiffs are Decedent's husband, Abdelmajid Elmazouni, and his children, who bring this action individually and as the heirs and/or legal representatives of Decedent and her estate. *Id.* at 2, ¶¶1.01-1.02. By their Original Complaint, Plaintiffs allege that, during Decedent's hospital admission on February 24, 2014, a doctor wrote her a prescription for fentanyl patches, marketed and sold by Defendants (the "Mylan patch"). *Id.* at 4, ¶¶4.02-4.03 & 5, ¶4.06. Plaintiffs allege that Decedent filled the prescription on February 26, 2014, and used the Mylan patch from February 27, 2014 to March 1, 2014,

during which time she was readmitted to the hospital due to continued, increasing pain. *Id.* at 5, ¶4.06. Plaintiffs further allege that, following her discharge from the hospital on March 1, 2014, Decedent experienced complications, including increased pain, severe constipation, and bloating. *Id.* at 6, ¶4.08. On March 2, 2014, an ambulance transported Decedent back to the hospital, where she arrived not breathing and unconscious. *Id.* Decedent died later that day. *Id.* Plaintiffs allege that Decedent had a fatal fentanyl blood concentration at the time of her death, and her autopsy report states that she died as a result of the toxic effects of fentanyl. *Id.*

According to Plaintiffs, the Mylan patch is designed to transmit a specific amount of fentanyl into a patient through the skin, at a certain rate over an extended period of time. *Id.* at 5, ¶4.04. Plaintiffs allege, however, that the Mylan patch is unreasonably dangerous because it can and does function improperly, causing lethal levels of fentanyl in patients using the Mylan patch. *Id.*, ¶4.05. Plaintiffs allege that Defendants were aware of and had knowledge that certain of the Mylan patches were defective and had the propensity to cause severe injury and death. *Id.* at 6, ¶4.07. Based on the facts alleged, Plaintiffs assert seven causes of action against Defendants: (1) strict product liability under Section 402A and 402B of the Restatement (Second) of Torts; (2) negligence; (3) negligent representation; (4) breach of the implied warranty of fitness; (5) violations of the Texas Deceptive Trade Practices Act ("DTPA"); (6) violations of Texas Business and Commerce Code Section 2.314(b)(1)-(b)(6); and (7) gross negligence.[1]

[1] The parties agree that Texas substantive law applies in this diversity case. *See McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 702 (5th Cir. 2014) (under Texas choice of law principles, Texas had the "most significant relationship," and thus Texas substantive law applied to, pharmaceutical product liability action brought by Texas resident who was treated with the accused product in Texas).

Defendants move to dismiss Plaintiffs' Original Complaint for failure to state a claim. Defendants argue that Plaintiffs' allegations are insufficient to satisfy federal pleading standards and that several of Plaintiffs' claims are foreclosed by Texas law, including Plaintiffs' strict liability and DTPA claims. Defendants further argue that all of Plaintiffs' claims relating to the design of the Mylan patch and its accompanying warnings are preempted by federal law.

The issues have been fully briefed, and Defendants' Motion to Dismiss is ripe for determination.

Legal Standards

Rule 8(a) requires that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). To satisfy plausibility, a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The plausibility standard requires more than a sheer possibility that a defendant acted unlawfully, and a plaintiff's factual allegations "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

Analysis

Preliminary Matters

Defendants ask the Court to take judicial notice of the content of two documents submitted in support of their Motion to Dismiss: (1) a copy of a letter from the Food and Drug Administration ("FDA") dated January 28, 2015, approving Defendants' Abbreviated

New Drug Application to market the Mylan patch ("Approval Letter"); and (2) a copy of the Full Prescribing Information for the Mylan patch (the "Label"). *See* Def. App. [ECF #7] 1-3; *id*. at 4-13. The Approval Letter states the FDA determined that the Mylan patch, a generic fentanyl transdermal system, was "bioequivalent" and "therapeutically equivalent" to the reference listed drug, Duragesic Transdermal Systems, manufactured by Alza Corp. *See id.* at 1. The Approval Letter further states the FDA concluded the Mylan patch is "safe and effective for use as recommended in the submitted labeling." *Id.* The Label for the Mylan patch provides that the product is "intended for the management of persistent, moderate to severe chronic pain in opioid-tolerant patients 2 years of age and older when a continuous, around-the-clock analgesic is needed for an extended period of time." *Id.* at 4. The Label also includes a "black box" warning that states:

> **Fatal respiratory depression could occur in patients who are not opioid-tolerant and in patients that are opioid-tolerant even if fentanyl transdermal systems is not misused or abused.**

Id.

When ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court must take the allegations in the complaint as true and resolve any ambiguities or doubts as to the claims' sufficiency in favor of the plaintiff. *Jones v. Alcoa, Inc*., 339 F.3d 359, 362 (5th Cir. 2003). "However, courts may also consider matters of which they may take judicial notice." *Lovelace v. Software Spectrum, Inc*., 78 F.3d 1015, 1017–18 (5th Cir. 1996) (taking judicial notice of public disclosure documents in a securities fraud case); *see also* Fed. R. Evid. 201(f) ("Judicial notice may be taken at any stage of the proceeding."). Courts may take judicial notice of an "adjudicative fact" if the fact "is not subject to reasonable dispute

because it (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b).

Here, Plaintiffs acknowledge that the Approval Letter and the Label are publicly available documents, the contents of which are not subject to reasonable dispute. Pl. Resp. [ECF # 8] at 9. In particular, Plaintiffs do not dispute either that the FDA approved the Mylan patch for marketing as the generic equivalent of Alza Corp.'s Duragesic Transdermal Systems or that the Label contains a black box warning regarding fatal respiratory depression. Therefore, the Court will take judicial notice of the contents of the Approval Letter and the Label. *See Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011); *see also Gonzalez v. Bayer Healthcare Pharm., Inc.*, 930 F. Supp. 2d 808, 811 (S.D. Tex. 2013) (taking judicial notice of FDA approval letter for prescription drug); *Cooper v. Pfizer, Inc.*, 2015 WL 2341888, at *2 & n.1 (S.D. Tex. May 13, 2015) (taking judicial notice of the contents of an FDA approved label).

Strict Liability

Plaintiffs' first cause of action is a strict product liability claim, which is governed by Section 402A of the Restatement (Second) of Torts. Pl. Compl. at 6-7, ¶¶5.02-5.05; *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 334–35 (Tex. 1998) (holding that Texas follows the Restatement (Second) of Torts in product liability cases). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm caused to the ultimate user or consumer, or to his property, if
>
> > (a) the seller is engaged in the business of selling such a product, and

> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402A. "To make out a strict liability cause of action, a party must establish that: (1) a product is defective; (2) the defect rendered the product unreasonably dangerous; (3) the product reached the consumer without substantial change in its condition from the time of original sale; and (4) the defective product was the producing cause of the injury to the user." *Syrie v. Knoll Int'l*, 748 F.2d 304, 306 (5th Cir. 1984). A product may be unreasonably dangerous because of a defect in marketing, design, or manufacturing. *See American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). In this case, Plaintiffs allege the Mylan patch was unreasonably dangerous due to a defect in marketing, design, and manufacturing.

Plaintiffs allege that the Mylan patch was defective because of a "manufacturing flaw." Pl. Compl. at 7, ¶5.07. "A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006) (quoting *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004)). Plaintiffs allege that the patch used by Decedent was defective because "it malfunctioned and did not perform as intended or designed." *Id.* at 8, ¶5.09. Plaintiffs allege that the Mylan patch is

intended and designed to release a specific amount of fentanyl into a patient's bloodstream at a certain rate. *See id.* at 5, ¶4.04. "[I]f functioning properly, the patient should not receive a harmful dose of [f]entanyl." *Id.* Plaintiffs further allege that, at the time of her death, Decedent had a lethal fentanyl blood concentration and died as a result of the toxic effects of fentanyl. *See id.*, at 6, ¶ 4.08. Defendants argue that these allegations are insufficient to state a claim based on a manufacturing defect. The Court agrees.

Plaintiffs fail to allege any specific manufacturing defect. Rather, Plaintiffs argue that, because Decedent's cause of death was fentanyl toxicity, there must have been a manufacturing defect. Texas law does not permit the inference of a defect to be drawn from the mere fact of a product-related accident. *See Mendez*, 204 S.W.3d at 807; *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 601 (Tex. 2004). Allegations which rely on *res ipsa loquitor* are not sufficient to state a product liability claim based on a manufacturing defect. *See Funk*, 631 F.3d. at 782. Plaintiffs' conclusory allegations that a manufacturing defect existed in the manufacture of the Mylan patch fall short of what is required to state a manufacturing defect claim. *See Eckhardt v. Qualitest Pharm. Inc.*, 858 F. Supp. 2d 792, 800 (S.D. Tex. 2012), *aff'd*, 751 F.3d 674 (5th Cir. 2014) (conclusory allegations that manufacturing defect existed in manufacture of generic drug failed to state manufacturing defect claim against manufacturers under Texas law). Therefore, this claim will be dismissed without prejudice.

Plaintiffs further allege that Defendants are strictly liable for Decedent's death because they failed to provide adequate warnings and instructions to consumers regarding the reasonably foreseeable risks of serious harm associated with the Mylan patch. *See* Pl. Compl. at 8-9, ¶¶5.12-5.13, 5.16; 10-11, ¶¶5.20-5.21; 12-13, ¶¶5.26-5.28; 14, ¶5.35; 15, ¶¶5.38, 5.39. Plaintiffs contend that Defendants' alleged failure to provide adequate warnings rendered the

Mylan patch defective, for which Defendants should be held strictly liable under Texas law. *Id.* at 8, ¶¶5.12-5.13. Plaintiffs further allege that the Mylan patch was defectively designed. *Id.* at 9-10, ¶¶5.15-5.16. Defendants contend that Plaintiffs' failure to warn and design defect claims are preempted by federal law.

Federal law requires a generic drug to have the same chemical composition and labeling as its brand-name counterpart. *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2471–2475 (2013). ("[T]he FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand name drug on which it is based."). This federal "duty of sameness" preempts state-law claims against a generic drug manufacturer that would require the manufacturer to redesign its drug or change its labeling. *Id.* at 2474–77; *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). *See also Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 611–13 (5th Cir. 2014) (failure to warn and design-defect claims against generic manufacturers preempted by federal law); *Eckhardt*, 751 F.3d at 678–79 (same). The Fifth Circuit has adopted a broad interpretation of the principle of federal preemption as it applies to claims against generic drug manufacturers and has upheld dismissals of a wide variety of claims whose factual allegations boil down to complaints of "failure to warn" or "design defect." *See, e.g., Lashley v. Pfizer, Inc.*, 750 F.3d 470, 474 & n. 3 (5th Cir. 2014); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013).

Here, the Mylan patch is the FDA-approved generic bioequivalent of Alza Corp.'s Duragesic Transdermal Systems. *See* Def. App. at 1. All of Plaintiffs' state law tort claims based on an alleged failure to provide adequate warnings regarding the risks associated with the Mylan patch or any alleged design defect that rendered the product unreasonably unsafe would require Defendants to have provided different warnings or altered the chemical

composition of the Mylan patch. Such claims therefore conflict with federal law requiring Defendants to conform the Mylan patch and its accompanying warnings to the equivalent brand name product. Because Plaintiffs' claims premised on an alleged failure to warn or design defect conflict with federal law, they are preempted. Defendants' motion to dismiss is granted with respect to Plaintiffs' claims based on allegations that Defendants failed to provide adequate warnings about, or defectively designed, the Mylan patch. Those claims are dismissed with prejudice.

Plaintiffs' failure to warn claims also fail for a second reason. Under Texas law, all of Plaintiffs' claims based on a failure-to-warn theory are governed by Section 82.007 of the Texas Civil Practice and Remedies Code, which provides that a pharmaceutical manufacturer is entitled to a rebuttable presumption that it is not liable for failure to warn if the FDA approved the warnings and information that accompanied the product. Tex. Civ. Prac. & Rem. Code § 82.007(a)(1); *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 379 (5th Cir. 2012). That presumption can only be overcome if Plaintiffs plead and prove one of several statutory exceptions, including that Defendants "withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." Tex. Civ. Prac. & Rem. Code § 82.007(b)(1). The Fifth Circuit has held, however, that the so-called "fraud-on-the-FDA" exception is preempted by the federal Food, Drug, and Cosmetic Act unless the plaintiff can show that "the FDA itself has found fraud." *Lofton*, 672 F.3d at 380. "[W]here the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA . . . [and is] a violation of the Supremacy Clause." *Id.*

Although Plaintiffs allege that Defendants were negligent in, among other things, failing to provide the FDA with information or data relevant to the safety of the Mylan patch, *see* Pl. Compl. at 10, ¶5.21(d), they have not alleged that the FDA found fraud. Thus, Plaintiffs' fraud-on-the-FDA allegation cannot be used to rebut § Section 82.007's presumption of non-liability for Defendants' alleged failure to warn. *Lofton*, 672 F.3d at 380. Plaintiffs' strict liability claims based on allegations that Defendants failed to provide adequate warnings about the Mylan patch are therefore dismissed with prejudice. *Id.*

Negligence

Plaintiffs' next cause of action is that Defendants were negligent in failing to exercise reasonable care in the design, manufacture, marketing, sale, and distribution of the Mylan patch. Pl. Compl. at 10-11, ¶¶5.20-5.21. Whether Plaintiffs seek recovery based on a negligence theory or a strict liability theory, they must establish that Decedent's injury resulted from a defect in the Mylan patch. *Toshiba Intern. Corp. v. Henry*, 152 S.W.3d 774, 784–85 & n.3 (Tex. App.—Texarkana 2004, no pet.). As stated above, Plaintiffs' Complaint fails to set forth sufficient facts to state a claim for manufacturing defect. Further, to the extent Plaintiffs' negligence claim is based on a purported duty to modify the warnings or design of the Mylan patch, it is preempted by federal law. *See Mensing*, 564 U.S. at 618; *Bartlett*, 133 S. Ct. at 2477. Defendants are therefore entitled to dismissal of Plaintiffs' negligence claim.

Negligent Misrepresentation

Plaintiffs' third cause of action is for negligent misrepresentation. Plaintiffs allege that Defendants knew that the Mylan patch created a high risk of unreasonable, dangerous side effects, including the risk that—even when properly used—the Mylan patch could cause

death. Pl. Compl. at 12, ¶5.26. Plaintiffs also allege that Defendants failed to properly communicate known risks to Decedent, physicians, other health care providers, and the general public, and instead marketed the Mylan path as safe and effective. *Id.* Plaintiffs further allege that Defendants are liable because they failed to provide "true and accurate information, warnings, and instructions" and failed to exercise reasonable care in "obtaining or communicating information regarding the safety and efficacy" of the Mylan patch to Decedent and others. *Id.*, ¶5.28. Defendants argue that these allegations are simply a restatement of Plaintiffs' failure to warn claim. The Court agrees. Accordingly, the Court determines that Plaintiffs' negligent misrepresentation claim is preempted by federal law, and Defendants are entitled to dismissal of this claim with prejudice.

Because the Court finds that Plaintiffs' allegations are merely a recasting of their failure to warn claim, it does not resolve Defendants' alternative argument that Texas does not recognize a tort for negligent misrepresentation leading to physical harm, but notes that this Court has previously found that at least one Texas court of appeals has recognized a cause of action for negligent misrepresentation where the plaintiff suffered physical harm, as provided for in the Restatement (Second) of Torts, §311. *Staples v. Merck & Co., Inc.*, 270 F. Supp. 2d 833, 840 (N.D. Tex. 2003) (Lynn, J.) (citing *EDCO Production, Inc. v. Hernandez*, 794 S.W.2d 69, 76–77 (Tex. App.—San Antonio 1990, writ denied)).

Implied Warranty of Fitness

Plaintiffs' fourth cause of action is for breach of the implied warranty of fitness. Pl. Compl. at 13, ¶5.31. Plaintiffs allege that the Mylan patch was designed, manufactured, marketed, and sold with the intention that it will continuously transmit fentanyl through the skin over an extended period of time. *Id.* at 5, ¶4.04. Plaintiffs further allege that the Mylan

patch was unfit for the particular purpose for which it was sold, and that this lack of fitness caused Decedent's death. *Id.* at 13, ¶¶ 5.31-5.32. Defendants argue that Plaintiffs' allegations are insufficient to state a claim for breach of the implied warranty of fitness.

Section 2.315 of the Texas Business and Commerce Code provides that "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish the suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Tex. Bus. & Com. Code § 2.315. To maintain a cause of action for breach of this implied warranty of fitness, a plaintiff must allege that the product at issue was to be used for some purpose other than the product's ordinary purpose. *Strauss v. Ford Motor Co.*, 439 F. Supp. 2d 680, 686 (N.D. Tex. 2006) (Fish, J.). In other words, "the particular purpose must be some unusual, out of the ordinary purpose peculiar to the needs of an individual buyer." *Coghlan v. Aquasport Marine Corp.*, 73 F. Supp. 2d 769, 774 (S.D. Tex. 1999); *see also* Tex. Bus. & Com. Code Ann. § 2.315, Comment (2) ("A 'particular purpose' differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question.").

Plaintiffs' Original Complaint fails to allege that Decedent purchased the Mylan patch for any purpose other than the product's ordinary purpose. Instead, Plaintiffs allege that the Mylan patch "is used for the management of persistent, chronic pain when continuous, around-the-clock pain relief is needed for an extended period of time" and that Decedent used the Mylan patch "for its intended purpose – the management of Decedent's chronic pain." *Id.* at 5, ¶4.04

& 7, ¶5.03. Because Plaintiffs do not allege that Decedent used the Mylan patch for a non-ordinary purpose, Plaintiffs have failed to state a claim for breach of the implied warranty of fitness. *Mehler Texnologies, Inc. v. Monolithic Constructors, Inc.*, 2009 WL 3149383, at *4 (N.D. Tex. Sep. 29, 2009) (Lynn, J.) (granting Rule 12(b)(6) motion to dismiss claim for breach of the implied warranty of fitness where plaintiff failed to allege, among other things, that the product at issue was to be used for some purpose different than the product's ordinary purpose). Defendants are thus entitled to dismissal of this claim without prejudice.

DTPA

Plaintiffs' fifth cause of action is for violations of the DTPA. Pl. Compl. at 14, ¶¶5.34-5.36. Plaintiffs allege that Decedent was a consumer as defined by the Tex. Bus. & Com. Code § 17.45, and Defendants were engaged in the business of designing, manufacturing, marketing, distributing, and selling pharmaceutical drugs for use by consumers. Pl. Compl. at 14, ¶ 5.34. Plaintiffs further generally allege that Defendants violated the DTPA by (i) representing that the Mylan patch was safe and effective, when it was not; (ii) breaching an implied warranty of merchantability; (iii) failing to disclose information regarding serious risks of harm involved with using the Mylan patch; (iv) representing that the Mylan patch had sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which it did not have, in violation of Section 17.46(b)(5); (v) advertising the Mylan patch with the intent not to sell the product as advertised, in violation of Section 17.46(b)(9); (vi) breaching an express or implied warranty, in violation of Section 17.50(a)(2); and (vii) committing an unconscionable action or course of action, in violation of Section 17.50(a)(3)). *Id.*, ¶5.35. Defendants contend that Plaintiffs' DTPA claim is invalid under Texas law because the DTPA does not apply to bodily injury or death, and because a

DTPA claim does not survive the death of the consumer. Plaintiffs do not address these contentions in their response to Defendants' Motion to Dismiss. Indeed, Plaintiffs fail to mention their DTPA claim at all. Therefore, the Court determines that Plaintiffs have abandoned their DTPA claim. *Black v. North Panola Sch. Dist.*, 461 F.3d 584, 588 n. 1 (5th Cir. 2006) (holding that a claim is considered abandoned when the plaintiff fails to defend it in response to motion to dismiss). Accordingly, the Court grants Defendants' Motion to Dismiss with respect to Plaintiffs' DTPA claim.

Even if Plaintiffs had not abandoned their DTPA claim, the Court would find dismissal proper. Although the Texas Supreme Court has not decided whether DTPA claims survive the death of the consumer, and there is no consensus on that issue among the intermediate state appellate courts, this Court has previously concluded that DTPA claims do not survive the death of the consumer.[2] *Boudreaux v. Corium Intern., Inc.*, 2013 WL 1890269, at *3 (N.D. Tex. May 7, 2013) (Lynn, J.); *see also Lofton v. McNeil Consumer & Specialty Pharm.*, 682 F.Supp.2d 662, 680 (N.D. Tex. 2010) (Lindsay, J.); *Launius v. Allstate Ins. Co.*, 2007 WL 1135347, at *6 (N.D. Tex. Apr. 17, 2007) (Boyle, J.).

Texas Business and Commerce Code

Plaintiffs' sixth cause of action is for breach of the implied warranty of merchantability in violation of Section 2.314 of the Texas Business and Commerce Code. Pl. Compl. at 15, ¶ 5.38. Plaintiffs allege that the Mylan patch was "unfit for the ordinary purpose for which it was used" because of unspecified "defects" and because of "a lack of something necessary for adequacy." *Id.* Under Texas law, strict liability for a manufacturing

[2] In light of the Court's conclusion that such claims do not survive the death of the consumer, the Court need not reach the issue of whether the DTPA applies to bodily injury.

defect and breach of an implied warranty of merchantability are two separate causes of action. *See Garcia v. Texas Instruments, Inc.*, 610 S.W.2d 456, 461–62 (Tex. 1980). However, depending on the facts of the case, whether a manufacturing defect exists for purposes of products liability often resolves whether a product was defective and, therefore, breached an implied warranty of merchantability. *See Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 666 (Tex. 1999) (recognizing that whether a defect exists for breach of an implied warranty of merchantability and for strict liability involves an identical factual determination). In this case, Plaintiffs do not dispute that their breach of warranty claim under Section 2.314 is functionally equivalent to their strict liability cause of action, and should survive or fail for the same reasons. *See* Def. Mot. at 24; Pl. Resp. at 19. For the reasons discussed above, the Court has determined that Defendants are entitled to dismissal of Plaintiffs' strict liability claim. Because Plaintiffs' breach of warranty claim under Section 2.314 is equivalent to its strict liability claim, Defendants are similarly entitled to dismissal of Plaintiffs' claim for breach of an implied warranty of merchantability.

Defendants further contend that dismissal is appropriate because Plaintiffs failed to allege that they provided pre-suit notice of the breach of warranty, as required under Texas law. Section 2.607(c)(1) of the Texas Business and Commerce Code provides that "[w]here a tender has been accepted . . . the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy[.]" Tex. Bus. & Comm. Code § 2.701(c)(1). The purpose of this requirement is to give the seller an opportunity to inspect the product to determine whether it was defective and to allow the seller an opportunity to cure the breach, if any. *Wilcox v. Hillcrest Memorial Park of Dallas*, 696 S.W.2d 423, 424 (Tex. App.—Dallas 1985, writ ref'd n.r.e.). A buyer's failure to

notify a seller, including a remote seller such as the manufacturer, of a product's alleged defect within a reasonable time of discovering the defect bars the buyer from recovering for a breach of warranty under Section 2.314. *Id.*; *U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 202 (Tex. App.—Houston [1st Dist] 2003, pet. denied); *Bailey v. Smith*, 2006 WL 1360846, at *4–5 (Tex. App.—Corpus Christi 2006, no pet.). *But see Vintage Homes, Inc. v. Coldiron*, 585 S.W.2d 886, 888 (Tex. App.—El Paso 1979, no writ) (holding the notice requirement applies only between buyer and immediate seller). Plaintiffs do not dispute that the notice requirement of Section 2.607(c)(1) applies to their breach of warranty claims under Section 2.314; nor do they allege that they provided the required notice to Defendants. Therefore, the Court determines that Plaintiffs' warranty claims should be dismissed for the additional reason that they failed to provide the statutorily required notice to Defendants prior to filing suit. *Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 970 (S.D. Tex. 2016) (dismissing claim for breach of implied warranty where plaintiffs failed to provide drug manufacturer with pre-suit notice of the product's alleged defect); *McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 915 (W.D. Tex. 2013), *aff'd*, 751 F.3d 694 (5th Cir. 2014) (same).

Gross Negligence

Plaintiffs' final cause of action is for gross negligence and is based on the same allegations as its claims for strict liability and negligence. Pl. Compl. at 15, ¶5.39. The Court has determined, however, that Plaintiffs' Complaint fails to state a claim for strict liability or negligence. Therefore, the Court determines that Plaintiffs' gross negligence claim must also fail.

Conclusion

Defendants' Rule 12(b)(6) Motion is GRANTED. Plaintiffs' claims based on an alleged failure to provide adequate warnings or a defect in the design of the Mylan patch, including their claims for strict product liability, negligence, gross negligence, negligent misrepresentation, and violations of the Texas DTPA and the Texas Business and Commerce Code, are preempted by federal law and are DISMISSED with prejudice. Plaintiffs' claims based on a manufacturing defect, including their claims for strict product liability and breach of an implied warranty of merchantability, as well as their claim for breach of an implied warranty of fitness are DISMISSED without prejudice.

Plaintiffs are hereby granted leave to file an Amended Complaint within fourteen days of the date of this Memorandum Opinion and Order to cure, if they can, Plaintiffs' claims based on a manufacturing defect and for breach of an implied warranty of fitness. Plaintiffs must file a redlined version of their Amended Complaint, showing all changes from the Original Complaint.

SO ORDERED.

December 1, 2016.

BARBARA M. G. LYNN
CHIEF JUDGE